

### **39 FDA Codes are Violated by Soy Isoflavones and Anti-nutrients:**

To: Expert Panel for review.

Violations of FDA Codes and Regulations regarding soy, and especially soy-based infant formulas are as follows:

- 1. ALLERGEN 403(w) 801(a)(3); Misbranding-** “The label fails to declare all major food allergens present in the product, as required by section 403(w)(1).”

Explanation- Soy is an established #2 allergen, just below peanuts. Soy-based formulas, milk formulas with soy added, foods and beverages with soy protein, soy lecithin, soy oil, etc, that are especially marketed to infants and children containing soy are not labeled as an allergen. Soy foods and beverages in general are not labeled as an allergen. Misbranded.

- 2. Bio Toxin 402(a)(1), 801(a)(3), Adulteration-** “.....appears to contain a poisonous and deleterious substance which would ordinarily render it injurious to health.”

Explanation- Soy isoflavones are established by CFSAN and multiple published studies as “estrogenic endocrine disruptors” that are biologically active phyto-estrogens proven to cause a variety of adverse hormone disrupting effects to multiple organ systems, throughout the body and brain. The several active estrogenic isoflavones found in soy products, including soy-based formulas (milk formulas are increasingly contaminated with soy) are proven to cause chromosome manipulations and DNA breakage that is known to be especially physiologically and neurologically damaging to fetus, infants and children. The FDA has no evidence as to which child might normally survive exposure(s) to soy phytoestrogens as well as the multiple anti-nutrients found in soy. Fluctuating levels of soy phyto-estrogens and soy anti-nutrients, known as soy phyto-toxins are not measured or labeled prior to marketing. Soy phyto-toxins are repeatedly proven as injurious to health, and largely so during developmental timeframe exposure(s). Adulterated.

- 3. DANGEROUS 502(j), 801(a)(3);Misbranding-** “....appears to be dangerous to health when used in the dosage or manner, or with the frequency or duration, prescribed, recommended, or suggested in the labeling thereof.”

Explanation- Soy phyto-estrogens are active endocrine disruptors that are often comparable to DES and estradiol, which are highly dangerous prescribed estrogens. Soy phyto-estrogen consumption during pregnancy is concluded as route of transfer of estrogenic chemicals to her fetus, as is maternal consumption of soy phyto-estrogens transferred to her infant while breast feeding. Soy-based formulas, milk formulas that contain soy, soy foods and beverages marketed directly and indirectly to infants and children are now consumer available in an excess of 2700 products. There exists overwhelming documented evidence that accumulating intake of soy phyto-estrogen

exposures results in highest risk for adverse biological effects. There is again overwhelming documented evidence that the younger the soy phyto-estrogen consumer the more biologically dangerous due to fragility, frequency, and duration. Soy-based formulas and milk formulas, soy infant cereals, cookies etc, are proven to be high dosages of soy phyto-estrogens and soy anti-nutrients, again excessive in duration and frequency of exposures. As equal to other potent estrogenic chemicals, soy should be prescribed for fetus, infant, and child consumption, especially in that there is no other estrogenic endocrine disruptor so overwhelmingly overdosed during these most fragile developmental timeframes. Hundreds upon hundreds of published studies conclude the causation of an assortment of soy phyto-toxic adverse health effects that are most often irreversibly damaging, the cause of children's pain and suffering through adulthood or until premature death.

- 4. DIOXIN 402(a)(1),402(a)(2)(A),402(a)(2)(C)(i), 801(a)(3)-Adulterated-** “The article appears to bear or contain dioxins and/or PCB compounds, poisonous or deleterious substances and/or unapproved food additives which may render it injurious to health.”

Explanation- Like soy, dioxins and PCB compounds are endocrine disruptors, deemed poisonous or deleterious substances. Soy phyto-estrogens are proven to be active endocrine disruptors, qualifying soy as a poisonous or a deleterious substance. Dioxin, PCB, or any other wide assortment of environmental endocrine disruptors, in combination with soy phyto-toxic endocrine disruptors is stated throughout published studies to increase adverse health risks even more than any one of these endocrine disruptors alone. Soy, as a recognized endocrine disruptor is the only endocrine disruptor that is directly marketed for deliberate human consumption; contaminating to fetus, to infants, and to children. Published study evidence concludes soy phyto-toxins are poisonous or deleterious substances, an unapproved food ingredient that is injurious to health particularly to fetus, infants, and children. Adulterated.

- 5. FALSE 502(a), 801(a)(3);Misbranding-** “The labeling for this article appears to be false or misleading.”

Explanation- Soy industry continues to promote unapproved soy products as “safe and nutritional,” for “brain and eye health” for “good health,” etc, while the extreme contrary is reported throughout a multitude of published studies. Soy phyto-estrogens and/or soy phyto-antinutrients, as active endocrine disruptors, are concluded throughout studies to cause irreversible physiological and neurological adverse events particularly due to repeated fetal, infant, and child dosages and duration of exposure to soy phyto-toxic endocrine disruptors. Misbranded.

- 6. FALSE 403(a)(1), 801(a)(3); Misbranding-** “The labeling appears to be false and misleading in any particular.”

Explanation- Same as above. Misbranded.

- 7. GINSENG 402(a)(2)(C) 801(a)(3); Adulteration-** “The article appears to bear or contain Ginseng, a food additive which is unsafe within the meaning of Section 409.”

Explanation- Like soy, ginseng is also a phytoestrogen. Phytoestrogens are dietary estrogens that have the ability to cause estrogenic or/and antiestrogenic effects of which is proven as especially causing adverse hormonal effects during developmental exposures. Interestingly, the FDA has declared Ginseng as “Adulteration under the food additive Section 409,” but not soy phytoestrogenic endocrine disruptors. And at the same time allowing increasing numbers (reportedly 2700) soy phyto-toxic foods and beverages to target infants and children, but not phytoestrogen ginseng. Ginseng phytoestrogen is declared under FDA Section 409 as “Adulteration” while soy phytoestrogen is not. Please explain.

- 8. INCONSPICUOUS 403(f), 801(a)(3); Misbranding-** “Information required by the Act to be on the label or labeling does not appear to be conspicuous enough as to render it likely to be read and understood by the ordinary individual under customary condition of purchase and use.”

Explanation- Soy labeling lacks information under the FDA labeling law for allergens. Soy labeling lacks information of fluctuating estrogenic endocrine disruptors, and phyto-anti-nutrient contents. Soy labeling lacks information about the multitude of published study evidence concluding an assortment of damaging health effects especially caused to exposed fetus, infants, and children. According to FDA codes, soy labeling is misbranded due to evidence that soy phyto-estrogens and soy antinutrients are transferred via the mother to fetus, and also to infant while breast feeding. Soy labeling lacks adverse health effects pertaining to overwhelming published study evidence concluding: thymus and/or thyroid damage, (hypothyroidism) gastrointestinal disorders, extensive reproductive damage, irreversible neurological disorders (autism, mental retardation, seizures, cerebral palsy, ADHD, etc, caused by overwhelming evidence that soy damages multiple neurotransmitter systems), immunodeficiency diseases, allergies, kidney, liver, and pancreatic disorders, diabetes, leukemia, cancers, cancer metastasis, and more. Soy labeling sorely FAILS to warn of a multitude of adverse health effects as published study and NIH concludes particularly during most vulnerable developmental exposures. Misbranded.

- 9. LABELING SECTION 4(a), 801(a)(3) Misbranding-** “The article appears in violation of FPLA because of its placement, form and/or contents statement.”

Explanation- Soy is increasingly added to milk infant formulas, and as a filler to increasing numbers of foods and beverages. Seldom are soy “Allergen” and other known soy phyto-toxic risks listed on soy products. Soy products: soy-based formulas, soy foods and beverages targeting infants and children, are NOT labeled as CFSAN recognized “estrogenic endocrine disruptors,” of which endocrine disruptors are well-known by the FDA as damaging to health and presenting highest health risk to fetus, infants, and children exposed. Soy products commonly promote false and misleading

claims, including labeling on infant formulas as: “nutritional” for “good health” for “brain health” for “eye health” and more.....ALL that has NOT been proven as true, and in fact on the contrary, soy estrogenic endocrine disruptors are overwhelmingly concluded to cause an assortment of irreversible physiological and neurological damaging effects with increasing health risk during developmental exposures as can be expected. The FDA has not proven or approved soy as safe or healthy, and the American public deserves this right-to-know the truth. Misbranded.

**10. LACK NOTIFICATION 301(s)-** “Adulterated, 801(a)(3), lack of documentation establishing that the infant formula meets all notification conditions required by 412(c) or 412(d), Prohibited Act, Section 301(s).”

Explanation- Soy formula is adulterated due to lack of documentation establishing that soy infant formula meets all nutritional contents required. Each and every soy formula can fluctuate in isoflavone estrogenic contents as well as soy anti-nutrient contents, and these phyto-toxins are damaging endocrine disruptors. Levels of soy anti-nutrients are well-known to cause dangerous essential mineral fluctuations, (too much or too little), while each and every soy infant formula is not measured or labeled for soy estrogenic isoflavones and soy anti-nutrients contents. Soy is a non-nutrient, soy protein contains estrogenic isoflavones, while the isoflavones are estrogenic endocrine disruptors found to be especially damaging during developmental exposure. Soy protein had not been proven as worth the extensive and irreversible adverse health risks caused by soy estrogenic disruptor actions. Any health benefit of soy-based infant formulas above the risk has NOT been proven. A multitude of essential minerals and nutrients must be carefully added to soy in varying levels due to soy’s high levels of anti-nutrients, as well as soy’s high levels of heavy metals as multiple published studies reveal. Besides evidence of soy-causation of excessive or deficient essential mineral levels, evidence of soy-causation of heavy metal contamination, and soy’s active estrogenic endocrine disruptors, soy also causes deficiencies in essential enzymes: thyroxine, trypsin, tyrosine, and topoisomerase, each and all of which are highly necessary for normal physiological and neurological infant development. There is no evidence that soy industry is carefully monitoring EACH soy formula product, and no evidence that soy industry can correct excessive amounts of soy’s estrogenic and anti-nutritional contents. Adulterated.

**11. LIST INGREDIENTS 403(i)(2), 801(a)(3);Misbranding-** “It appears the food is fabricated from 2 or more ingredients and the label does not list the common or usual name of each ingredient.”

Explanation- Soy contains to the least 3 active estrogenic isoflavones in varying levels: genistein, daidzein, glycitein. Soy contains extensive levels of anti-nutrients; phytic acid, enzyme inhibitors, lectins, hemagglutinins, cyanogens, saponins, nitrosamines, furan, of which NONE are properly labeled as contained in soy contents. During fetal, infant, and child development, each and all of these cause increasing risk of developmentally damaging effects. Misbranded.

**12. N-RX INACTIVE INGREDIENT 502(e)(1);801(a)(3); Misbranding-** “The article appears to be a nonprescription drug and fails to bear the established name of each inactive ingredient in alphabetical order on the outside container of the retail package.”

Explanation- Soy phyto-estrogens are FDA known as causing agonistic and antagonistic hormone effects. In accordance with FDA codes, soy must become labeled as containing estrogenic endocrine disruptors similar to prescribed DES and estradiol estrogenic drugs as multiple studies conclude. Soy is proven to have effects on both E<sub>R</sub>a and E<sub>R</sub>b estrogen receptors proving soy as an active estrogen and confirming greatest adverse health risks to fetus, infants, and children. Soy phyto-estrogens and soy anti-nutrients are all active biological phyto-toxic chemicals proven capable of causing alarming hormone manipulations and interruptions. Misbranding.

**13. NO LICENSE 502(f)(1), 801(a)(3);Misbranding & PHS Biological Act 351-** “The article appears to be a biological product not manufactured at an establishment holding an unsuspended and unrevoked license issued under the Public Health Service Act, Biological Products Section 351.”

Explanation- Soy industries are marketing biologically active estrogenic endocrine disruptors while not licensed to produce, market, advertise, sell and promote biologically active soy endocrine disruptors to fetus, infants, children or adults. Misbranded.

**14. NUTRITIONALLY DEFICIENT 412(a)(1), 801(a)(3); Adulterated-** “The infant formula appears to be adulterated in that it does not provide the nutrients required by 21 CFR 107.100.”

Explanation- The nutrients in soy are misrepresented in that there are more damaging risks, or adverse events in soy, qualifying industry claimed soy’s nutritional benefits as not relevant. Soy anti-nutrients are proven to largely fluctuate from batch-to-batch and demands intensive nutrient investigative research per each and every batch. Before and after the processing of soy-based formulas demands investigative nutrient quality which are seldom investigated, in that soy processing does not delete soy’s anti-nutrients or nutrient inhibitors, and the addition of nutrients (essential minerals) have been study reported as excessive or deficient and do not withstand beneficial infant development, while increasing risk. Soy’s natural heavy metal content is reportedly worsened after soy processing. Soy’s estrogenic endocrine disruptors are NOT eliminated during processing, and are also proven to cause deleterious developmental effects, many of which are irreversible. Adulterated.

**15. NUTRITIONAL LABELING 403(q); 801(a)(3); Misbranding-** “The article appears to be misbranded in that the label or labeling fails to bear required nutrition information.”

Explanation- Soy-based formula contains routine nutritional information while likely not relevant to a particular soy formula batch because of extreme fluctuations in soy

isoflavones and soy anti-nutrients per batch. Soy estrogenic endocrine disruptors delete any so-claimed nutritional value. Soy must reveal estrogenic isoflavone content as well as anti-nutrient content, as “active endocrine disruptors” on labeling or it is misbranded. Any nutritional value of soy products become invalid in comparison to the damage caused by soy endocrine disruptor effects especially during developmental exposures. Misbranded.

**16. OMITTED 402(b)(1), 801(a)(3), Adulteration-** “It appears that a valuable constituent of the article has been in whole or in part omitted or abstracted from the article.”

Explanation- The most prevalent or valuable constituent of soy; isoflavone estrogenic endocrine disruptors, proven as phyto-toxic poisons especially during developmental exposures are wrongly omitted from soy-formulas and all soy product labeling. Soy anti-nutrients that are also proven as damaging to health are also omitted from the article. Adulterated.

**17. OPTIONAL INGREDIENTS 403(g)(2), 801(a)(3); Misbranding-** “It appears to be a food for which a definition and standard of identity have been prescribed by regulations under section 401 and appears to not be labeled with the common names of the optional ingredients specified therein.”

Explanation- The American public, American parents do not know that they are feeding their babies estrogenic phyto-chemicals capable of estrogenic endocrine disruptor effects. Soy is also not labeled with the identity of the estrogenic ingredients or of soy anti-nutrients. Soy includes ingredients that are poisonous and deleterious substances (endocrine disruptors) which may render soy as injurious to the health, especially during developmental exposures, while not identified through the labeling as such. Misbranded.

**18. PB-FOOD 402(a)(1); 801(a)(3);Adulteration-** “The article is subject to refusal of admission pursuant to Section 801 (a) (3) in that it appears to contain a poisonous or deleterious substance, lead, which may render it injurious to health.”

Explanation- Soy is subject to refusal of admission because soy contains toxic levels of isoflavones and antinutrients known as injurious to health. Besides estrogenic isoflavones, soy is reported to contain: high levels of aluminum, deficient levels of zinc, excessive levels of calbindin D28k, excessive calcium, deficient levels of copper, deficient levels of iron, deficient levels of thiamin B1, cause unnatural manipulations of phosphorus, excessive levels of selenium, deficient levels of magnesium, contain toxic levels of manganese, contain excessive cadmium, excessive thallium, and causes lead toxicity. Soy is not labeled according to the known containment of poisonous and deleterious substances that are injurious to health particularly to fetus, infants, and children. Adulterated.

**19. PERSONAL RX 502(a) & (f)(1), 801 (a)(3); Misbranding-** “The article appears to be a drug which requires a prescription from your doctor.”

Explanation- Soy phyto-estrogens are active exogenous estrogenic phyto-chemicals overwhelmingly documented to cause endogenous estrogenic effects. Active estrogens are prescribed, with soy as the only phyto-estrogen exception. Soy, while not prescribed is an estrogenic endocrine disruptor often comparable to the estrogenic effects of DES and Estradiol that are prescribed. Soy is known to target and manipulate Estrogen Receptor Alpha as well as Estrogen Receptor Beta, qualifying soy as an equal to prescribed estrogen drugs. Soy-based formulas and increasing marketing of infant/child soy foods and beverages (including milk formulas) have become ubiquitous. There is no escape. There is no evidence that any certain child can normally survive soy estrogenic endocrine disruptor effects qualifying soy phyto-estrogens as an active estrogenic prescribed drug. Misbranded.

**20. PESTICIDE 402(a)(2)(B), 802(a)(B); Adulteration, and Pesticides**

**402(a)(2)(B) 802I(a)(B); Adulteration-** “The article is subject to refusal of admission pursuant to section 801(a)(3) in that it appears to be adulterated because it contains a pesticide chemical, which is in violation of section 402(a)(2)(B).”

Explanation- Soy is increasingly a genetically modified food source with implanted Round-up Ready pesticide gene Section 402 Adulterated Food is defined as “Poisonous....or deleterious ingredients.” Soy is proven to be both “poisonous” (estrogenic endocrine disruptor), and “deleterious” (loaded with antinutrients). Pesticide chemicals are endocrine disruptors, soy phyto-chemicals are endocrine disruptors. Pesticides carry warnings about toxic effects. Soy is directly fed to fetus, infants, and children without any warning of estrogenic endocrine disrupting effects. Adulterated.

**21. POISONOUS 402(a)(1), 801(a)(3); Adulteration, and 502(p),**

**801(a)(3); Misbranding and 402(a)(1), 801(a)(3): Adulteration-** “The article appears to contain a poisonous or deleterious substance, which may render it injurious to health.”

Explanation- Soy phyto-estrogens, and anti-nutrients as active estrogenic endocrine disruptors are “poisonous or deleterious substances,” that are overwhelmingly proven as injurious to health, particularly that of fetus, infants, and children, while not to exclude evidence of soy toxicity caused to adults. No one can say for sure who will survive and who will not survive the multiple soy phyto-toxic effects. Adulterated.

**22. REDUCED 501(d)(1), 901(a)(3); Adulteration-** “It appears to be a drug that a substance has been mixed or packed with so as to reduce its strength.”

Explanation- It is overwhelmingly documented that soy phyto-estrogens reduce the effects of various prescribed drugs such as Tamoxifen, and other hormone manipulating drugs. Soy products are not labeled as such. Oncologists often tell their cancer patients NOT to consume soy products, due to estrogenic effects known to metastasize cancer to fatal stages. Soy is well-known to cause estrogenic effects, while soy formula is directly

fed to infants as 100% of dietary intake for the long-term. Soy-based formulas cause destructive estrogenic effects, and cause once healthy infants to become diseased for a lifetime or until premature death.....the same for soy-exposed fetus, and soy-exposed children. Adulterated.

**23. RX LEGEND, 502(a) & (f)(1), 801(a)(3) Misbranding-** “The article appears to be a prescription drug without a prescription drug legend as required by Section 503(b)(4).”

Explanation- Soy is an estrogenic phyto-chemical, a phyto-toxin due to estrogenic effects. Soy-based formulas in Europe are most often prescribed. Soy-based formulas are not marketed and not popular in Asian countries. Soy as a known estrogenic endocrine disruptor has comparable effects to DES and estradiol estrogen drugs. Especially to infants and children, soy must become prescribed the same as other drugs causing estrogenic effects. FDA has no evidence to prove which fetus, infant, or child can survive soy phyto-estrogen effects. Soy is an active estrogen demanding RX labeling as equal to other active estrogens. Misbranded.

**24. RX COMPOUND 503(b)(4)(A) & 502(c), 801(a)(3); Misbranding-** “The labeling fails to bear, at a minimum, the symbol ‘RX only.’”

Explanation- Soy products, soy-based formulas, milk formulas with soy additives demand “at minimum” the “RX only” labeling. Misbranded.

**25. SACCHARIN 403(i); 803(a)(3) Misbranding-** “The article contains Saccharin, a non-nutritive sweetener, and its label or labeling fails to list it as an added ingredient.”

Explanation- Like Saccharin, this time it is soy that is a non-nutritive infant formula and non-nutritive food product of which labeling fails to list soy as an added ingredient to nearly 2700 foods and beverages. Soy is proven as potentially injurious to health, particularly during developmental stages. The risk-to-benefit ratio of soy estrogenic endocrine disrupting activities is equal to the guessing game of Russian roulette with greatest risks during developmental exposures. Misbranded.

**26. STARANISE 402(a)(2)(C)(i), 801(a)(3), Adulteration-** “The article appears to bear or contain a food additive, Japanese star anise, that is unsafe within the meaning of section 409”

Explanation- Star Anise is adulterated because it contains veranisatins in low concentrations, of which in infants “may be enough to produce adverse neurologic reactions...” Soy is adulterated because it contains soy phyto-estrogens and soy anti-nutrients as active endocrine disruptors, of which each one, and in combination can be referred to as soy phyto-toxic poisons. Estrogens target the brain. Soy phyto-estrogens disrupt and damage several neurotransmitter systems, of which alone and while causing



extensive cascading adverse neurological effects are stated to cause irreversible brain disorders such as autism, mental retardation, seizures, cerebral palsy, ADD, ADHD and more. No neurological disorder can be assumed that it was not caused to the fetus, infants, and children who were awash with brain-damaging soy endocrine disruptors. Adulterated.

**27. STD IDENT 403(g)(1), 801(a)(3); Misbranding-** “The food appears to be represented as a food for which definition and standard of identity have been prescribed by regulations as provided by section 401 and the food does not appear to confirm to such definition and standard.”

Explanation- In regards to soy products, inclusive of soy formula sold for infant consumption, and in violation of Section 401, soy manufacturers disseminate misleading information for their biologically active estrogenic endocrine disruptor products, while promoting soy as a health food product for good health. In truth soy is a biologically active estrogenic hormone disruptor capable of a number of damaging health effects particularly during developmental exposures..... and hereafter. Misbranded.

**28. STD QUALITY 403(h)(1), 801(a)(3); Misbranding-** “The article appears to be represented as a food for which a standard of quality has been prescribed by regulation as provided by Sec. 401 and it appears it quality falls below such standard and its label does not so indicate.”

Explanation- Soy product standard of quality is not proven upon marketing to consumers, because the soy isoflavone and soy anti-nutrient levels are not investigated upon each and every batch. Too often the consumption of soy estrogenic and soy anti-nutrient endocrine disruptors in marketed soy products can result in higher health risk levels than any manufacturer reported benefit. Too often the soy product manufacturer falsely labels soy benefits that are deliberately misleading and never proven. Misbranded.

**29. SUBSTITUTE- 501(d)(2), 801(a)(3); Adulteration-** “It appears to be a drug that a substance has been substituted wholly or in part.”

Explanation- Soy phytoestrogens acting as estrogenic endocrine disruptors are known as comparable to levels of prescribed estrogen drugs. Soy phytoestrogens are known to increase or antagonize estrogenic levels. Consumption of soy is well-known to react in relation to DES and/or estradiol estrogens, as well as anti-estrogen drugs, displaying estrogenic effects on the many hormone receptors throughout the body and brain. Soy is indicated throughout multiple studies to increase or antagonize estrogenic drug effects that are particularly dangerous during developmental exposures. Adulterated.

**30. SULFITEBL 403(a)(1),801(a)(3); Misbranding-** “The article is subject to refusal of admission pursuant to section 801(a)(3) in that it appears to be misbranded because 1) it appears to contain sulfites but the label fails to declare the presence of sulfites.....”

Explanation- 2004, C. J. Stine et al report that “Commercial isolated soy proteins (ISP) contains 22 and 31 ppm sulfite as measured.” Soy-based formulas contain sulfite and fetal, infant and child exposures to sulfites can cause neurological damage and early death. The amount of sulfite levels in isolated soy proteins sold as infant formulas, directly fed to babies must become labeled as in all soy products. Misbranded.

**31. UNAPPROVED- 505(a), 801(a)(3);Unapproved New Drug-** “The article appears to be a new drug without an approved new drug application.”

Explanation- Multiple published studies repeatedly conclude soy is an active estrogenic endocrine disruptor. Soy phyto-estrogens target estrogen receptors resulting in agonistic and antagonistic estrogenic effects, qualifying soy consumption with extensive disruptive estrogenic drug effects particularly to fetus, infants, and children. Soy estrogens equate to the hormone effects of prescribed estrogen drugs. Soy is without drug approval.

**32. UNFIT4FOOD 402(a)(3), 801(a)(3) Adulteration-** “The article is subject to refusal of admission pursuant to section 801(a)(3) in that it appears to be unfit for food [Adulteration, 402(a)(3)].”

Explanation- Soy is repeatedly proven as an unfit food for fetus, infant, children, and in fact some adults. Soy phyto-estrogens and soy antinutrients are each and all proven as phyto-toxic or poisonous for consumption particularly during developmental exposures. There is no opportunity to know which child may normally survive soy’s multiple toxic effects, and which once healthy child will become diseased. Adulterated.

**33. UNSAFE SUB 402(a)(2)(A), 801(a)(3); Adulteration-** “The article appears to bear or contain a substance which is unsafe within the meaning of Section 406.”

Explanation- Soy-based infant formulas contain phyto-estrogenic and anti-nutrient endocrine disruptors that contain: “unavoidable added poisons or deleterious substances” as described under Section 406. There is no evidence of which healthy fetus, infant, or child can or can not survive the toxic contents of soy products and soy-based formulas, and therefore soy phyto-chemicals are unsafe within the meaning of Section 406. Adulterated.

**34. UNSFDIETLB 402(f)(1)(A), 801(a)(3) Adulteration-** “The article appears to be a dietary supplement or contain a dietary ingredient that presents a significant or unreasonable risk of illness or injury under the conditions of use set out in the labeling or if none are set out in the labeling, under customary conditions of use.”

Explanation- Soy supplements do not carry WARNING LABELS of damaging effects to the fetus exposed to high levels during maternal consumption of soy phyto-estrogens and soy phyto-antinutrients. Soy supplements are reported to also cause damage to reproductive system functions of both men, and women, (to include the cause of infertility, cancers and metastasis). Note that it has been reported that the soy-contaminated sperm can cause damage if conception should take place. There is the

report of increased fetal miscarriage due to adult soy consumption or potential for fetus to survive with chromosome damage. Soy as an active endocrine disruptor is known to encourage the causation of chromosome damage and DNA breakage. Adulteration.

**35. UNSFDIETUS 402(f)(1)(D), 801(a)(3)Adulteration-** “The article appears to be a dietary supplement or ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury.”

Explanation- Soy supplements are loaded with phyto-toxins, with evidence of the cause of excessive estrogen levels that are health-threatening to both men and women, while largely health-threatening to fetus, infants, and children. Adulteration.

**36. USUAL NAME- 403(i)(1), 801(a)(3); Misbranding-** “It appears that the label does not bear the common or usual name of the food.”

Explanation- Soy products including soy-based formulas and soy foods/beverages marketed to infants and children “do not bear the common or usual name of the (soy) food” such as soy phyto-estrogens as active estrogenic endocrine disruptors, or the soy containment of multiple anti-nutrients such as sulfites, phytic acid, inhibitors, and many more. Soy products are also contaminated with highest levels of corn syrup and sugars that are NOT healthy. Multiple soy phyto-toxic-chemicals that are especially proven as physiologically and neurologically damaging to fetus, infants and children do NOT appear on the labeling of any soy products including those consumed during pregnancy and those soy products specifically targeting infants and children. Misbranded.

**37. VITAMNLBL 403(a)(2), 801 (a)(3); Misbranding-** “The food appears to be subject to section 411 and its advertising is false or misleading in a material respect or its labeling is in violation of section.”

Explanation- The vast majority of soy consumers (of soy supplements, foods, beverages) are not able to know they are consuming high levels of estrogenic endocrine disruptors and anti-nutrients which calculate to high levels of soy-phyto-poisons, resulting in reversible and more often irreversible damaging health effects. Misbranded.

**38. WARNINGS 502(f)(2), 801(a)(3); Misbranding-** “It appears to lack adequate warnings against use in a pathological condition or by children where it may be dangerous to health or against an unsafe dose, method, administering duration, application, in manner/form, to protect users.”

Explanation- Clearly and without question there is a tremendous lack of adequate WARNING LABELS on soy products/soy-based formulas that are confirmed as potent estrogenic endocrine disruptors and loaded with anti-nutrients that are overwhelmingly proven as especially physiologically and neurologically health-damaging to fetus, infants and children exposed, while highly capable of causing pain and suffering for a lifetime or

until premature death. It is well-known that the younger exposure to soy phyto-toxins and the longer duration, increases adverse health risks especially of once healthy fetus, infants, and children. With increasing soy added to foods and beverages, there is rarely an escape from soy phyto-toxins. Soy is increasingly overdosed to fetus, infants, children, as all adults living in the USA without adequate warning. More evidence of lacking adequate WARNING labels, oncologists commonly insist that their patient(s) stay away from soy products due to soy-estrogenic promotions of cancer, known as metastasis, the highly painful cause of cancer death. Soy is also concluded as the cause of several estrogen responsive cancers. Misbranded.

**39. WRONG IDEN 403(b), 801(a)3; Misbranding-** “The article appears to be offered for sale under the name of another food.”

Explanation- Soy carries wrongful label identity abusing the terms: natural, safe, and healthy, largely due to industry advertising manipulations. Soy is an active phyto-estrogen. Soy is a highly dangerous estrogenic endocrine disruptor. Soy is loaded with damaging anti-nutrients. Soy contains outrageous amounts of sugars/corn syrup known as damaging to health. Worth stating again, soy is labeled under the false connotations of safe and healthy, which is NOT the equal truth of soy as biologically phyto-toxic. Soy is now contained in an estimated 2700 foods without proper labeling of containing and causing soy phyto-toxic effects. There is rarely an escape from availability of soy phyto-toxins in the USA marketplace. Misbranded.

Presented by:

Gail Elbek

